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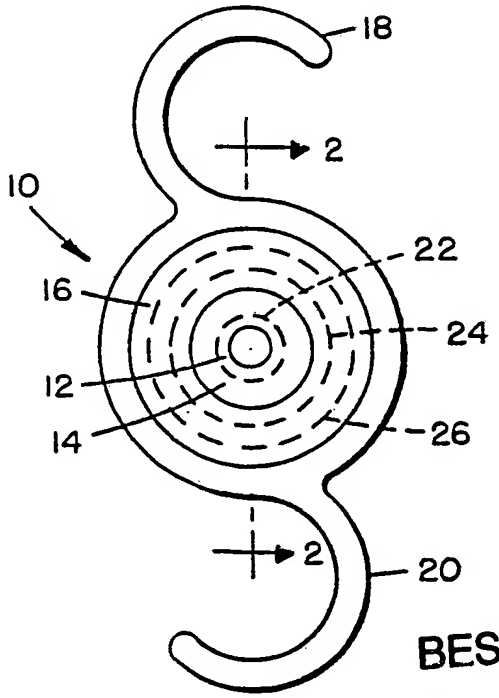
(54) Title: MULTI FOCAL INTRA-OCULAR LENS



(57) Abstract

The invention comprises an IOL with at least a center zone and two concentrically located ring zones arranged thereabout, the center zone having a distance power correction. The first concentric ring zone has a near power correction and the second concentric zone a distance power correction. In one embodiment the lens body is provided with haptics which act to center the lens body when it is surgically implanted within the posterior lens capsule. In other embodiments, the lens diameter is increased to mate with the internal dimensions of the posterior lens capsule or is provided with an encircling haptic which bears against the posterior lens capsule.

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MULTI FOCAL INTRA-OCULAR LENS

FIELD OF THE INVENTION

This invention relates to intra-ocular lenses (IOL) and, more particularly, to an improved multi-focal intra-ocular lens.

BACKGROUND OF THE INVENTION

Over the past several decades, it has become a common place surgical procedure to replace an opacified lens in the human eye with an artificial single power IOL. Such replacements have seen wide success. Until recently, the employment of multi-focal IOL's had not been considered seriously. However, with advances in the state of the art in multi-focal contact lenses, physicians are proceeding with the implantation of multi-focal IOL's.

Some of the more successful contact lenses of the multi-focal type are called "simultaneous image lenses". Those lenses are characterized by an aspheric anterior and/or posterior surface and by a continuously changing power from the para-central area to the mid-periphery. Lenses of this type are described in U.S. Patents 3,031,927 to Wesley; 3,037,425 to DeCarle and 4,636,049 to Blaker. The Wesley lens includes a small center zone for near vision surrounded by a concentric distance correction

zone. The DeCarle lens includes an opposite construct wherein the distance zone is in the center and is surrounded by the near correction zone. Blaker, describes a lens similar to the Wesley lens, however, he indicates that the near zone center section should be approximately equal to half the pupil area of the eye under average light reading conditions. The latter consideration indicates one of the problems with these lenses - i.e. that they are affected by the pupil size in that the pupil must be large enough to let enough light through the higher add zone of the lens to provide true bifocal action. Lenses of the Wesley/Blaker type are called reverse centrad bifocals.

One significant problem with the reverse centrad bifocals is that during outdoor activities in bright light, or in the presence of a bright illumination at night (e.g. such as driving a car in the presence of oncoming traffic), pupillary constriction reduces the proportion and percentage of rays of light that pass through the distance outer zone thus reducing the quality of distance vision. In fact, if there is sufficient pupillary constriction during the day or as a result of the headlights from oncoming vehicles at night, substantially all distance vision may be lost. This is obviously unacceptable - especially when it is considered that such a loss, when driving a car or as a pedestrian, is life threatening.

Recently, Nielsen at the Center for Eye Surgery in Clearwater, Florida has implanted bifocal IOL's employing the designs suggested by Wesley and Blaker. Those lenses were implanted in a number of patients and

were reported as providing "successful results". (see Ophthalmology Times volume 11, number 9, May 1, 1986, pages 1, 77 and 78).

Nielsen's implanted lenses experience the same defects as the reverse centrad bifocal lenses, i.e during activities outdoors in bright light or at night when driving a car in oncoming traffic conditions, pupillary constriction reduces the proportion and percentage of rays of light that can be perceived from the distance (outer) zone and thus reduces the quality of distance vision.

German Published Patent Application DE 3332313 A1 (U.S. 4,813,955) describes a multifocal intra-ocular lens wherein the near and far regions of the lens have approximately equal surface proportions and are symmetrically disposed as increasing concentric circles. The patent teaches that the approximate 50/50 ratio of surface areas of near and far correction regions is to be kept constant. This constraint creates problems in low light situations, i.e. at night. As the pupil enlarges, half the light is focused for near vision and half for far vision. This reduces the light utilizable for either far or near vision to one half the available light and significantly reduces the ability to see at night.

If a design is chosen which utilizes a far vision center zone, the lens is restricted to 50% or greater far vision. This design does not offer a combination of dimensions which would allow a more than 50% near vision under preferred reading conditions.

Accordingly it is an object of this invention to provide an improved bifocal IOL which preserves distance vision under all circumstances.

It is a further object of this invention to provide an improved bifocal IOL which preserves distance vision while also enhancing near vision under moderate light conditions.

It is another object of this invention to provide an improved bifocal IOL which is particularly adapted to insertion into the posterior lens capsule.

SUMMARY OF THE INVENTION

The invention comprises an IOL with at least a center zone and two concentrically located ring zones arranged thereabout, the center zone having a distance power correction. The first concentric ring zone has a near power correction and the second concentric zone a distance power correction. In one embodiment the lens body is provided with haptics which act to center the lens body when it is surgically implanted within the posterior lens capsule. In another embodiment, the greater proportion of the lens' correction zones are devoted to distance power corrections.

In a second embodiment, the lens diameter is increased to mate with the internal dimensions of the posterior lens capsule.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is a plan view of an IOL embodying the invention.

Fig. 2 is a sectional view of the invention taken along line 2-2.

Fig. 3 is a section view of an eye with the lens of this invention implanted in the posterior lens capsule.

Fig. 4 is a plan view of an IOL embodying the invention with a circular haptic.

Fig. 5 is a plan view of an IOL embodying the invention with enhanced bright and low light distance power corrections.

Fig. 6 is a side view of the lens of Fig. 5 and shows representative dimensions for the lens' correction zones.

Fig. 7 is a plot which shows the dominant affect of the distance correction zones of a lens incorporating the invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to Fig. 1, there is shown a plan view of a bifocal IOL particularly adapted to implantation in the posterior lens capsule. Lens body 10 is formed of a single piece of plastic material, such as silicone,

PMMA, other acrylates, polycarbonates, hydrogels or similar optically suitable materials. The lens is comprised of three correction zones, a circular zone 12 having a distance power correction; a concentrically arranged near power correction zone 14 and a second concentrically arranged distance power correction zone 16. A pair of haptics 18 and 20 are integrally formed with lens 10 and provide the centering facility for the lens when it is implanted in the posterior lens capsule. In the conventional manner, haptics 18 and 20 are flexible and bear against the inner surfaces of the lens capsule to center lens 10 subsequent to its implantation.

Dotted circles 22, 24 and 26 are representations of average pupillary openings under expected bright light conditions, average light conditions and low light conditions respectively. Pupillary openings 22, 24 and 26 are approximately 2mm, 4mm, and 6mm in diameter. The 2mm dimension is the smallest pupillary opening achieved under extreme bright light conditions or with the use of drugs to restrict the pupil, i.e., Miacol Pilocarpine. Under moderate light conditions the pupil ranges from 2.7 to 4.0mm. The 4mm dimension approximates the largest pupil opening involved for near vision. In dark conditions, the pupil expands beyond 4mm. The 6mm dimension approximates an average pupil in low light conditions. The preferred dimensions of the correction zones of IOL 10 are indicated in the side view of lens 10 in Fig. 2. Center zone 12 is approximately 1.0mm in diameter; first concentric near zone 14 has a preferred radial width in the range of 1.15mm to 2.12mm and the outer

diameter of lens 10 has a preferred overall range of from 5mm to 9mm.

With the above noted zone dimensions, it can be seen that under expected bright light conditions, the diameter of zone 12 is less than the expected minimum pupillary diameter 22 and assures continual distance vision. Under low light (dark) conditions, the width of concentric zone 16 is such as to enable substantial amounts of distance light to enter pupillary opening 26. It can further be seen that if the pupil expands further than is shown by dotted line 26, that distance corrected light entering the pupillary opening increases as the square of the radius thus enabling improved distance vision even under low light conditions.

Referring now to Fig. 3, lens 10 is shown implanted in the posterior lens capsule 30. The focal planes for all of the segments of IOL 10 fall on the macular portion of the retina and provide simultaneous images. As shown in Fig. 2, posterior surface 32 of lens 10 has a convex form which conforms to the posterior portion of lens capsule 30 to thereby avoid protein build up between the posterior portion of the lens and the capsule. The posterior surface may also be configured as a plane or meniscus.

Another IOL lens configuration made in accordance with this invention is shown in Fig. 4 and includes a central optic 50, a haptic 52 which fully encircles the optic and one or more struts 54 which attach the haptic to optic 50. Optic 50 is further provided with

identical correction ring zones to the IOL shown in Fig. 1.

Referring now to Figs. 5 and 6, an IOL is shown wherein the diameter of central distance correction zone 12 is increased to approximately 2.1mm. This enables the maximum amount of distance corrected light to enter the eye under extreme bright light conditions and preserves the best available distance vision under the circumstances. It can be appreciated that the diameter of the distance correction zone 12 still has a diameter less than the average pupil diameter (3.0mm) under moderate light conditions and provides true bifocal action.

From an examination of the IOL's shown in Figs. 1 and 2 and Figs. 5 and 6, it can be seen that in each, a greater percentage of lens area is devoted to distance vision than near vision. This is especially important in low light (dark) conditions, where it is desired to maximize the light gathering distance correction surface area. A plot is shown in Fig. 7, of the percentage of area available for distance and near correction under various pupil diameters for a lens incorporating the invention, e.g., such as the lens of Figs. 5 and 6. Under most conditions, except for moderate light conditions which are optimal for reading (pupil diameters 3.0-4.0mm), more than 50% of the IOL's light gathering surface area exposed by the pupil is devoted to distance correction. This assures maximum user safety while providing good light gathering capabilities for reading.

It should be understood that the foregoing description is only illustrative of the invention. Various alternatives and modifications can be devised by those skilled in the art without departing from the invention. For instance, while the IOL of this invention has been shown implanted in the posterior lens capsule, it may also be implanted in the anterior chamber or in the iris plane. Furthermore, while only two haptics are shown, more may be employed (e.g. three or four) or the lens can be made as a disk which is either flexible, rigid or a combination thereof. In such latter construct, the diameter of the disk is adjusted to mate with the internal dimensions of the posterior lens capsule.

While the ring correction zones have been shown as arranged on the anterior surface of the optic, it is also contemplated that the ring zones may be on the posterior surface of the optic or there could be a combination of rings on the posterior and anterior surfaces which, in combination, provide the desired corrections. If all or some of the ring zones are resident on the posterior surface of the optic, the anterior surface may be concave, plane or convex.

Further, the lens may be constructed of multiple pieces with the haptic constructed from material the same as the optic (e.g., PMMA) or a different material (e.g., polypropylene). These materials are permanently attached to the optic using suitable attachment means.

Accordingly, the present invention is intended to embrace all such alternatives, modifications and

variances which fall within the scope of the appended claims.

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CLAIMS

I Claim:

1. An intra-ocular lens comprising:

a lens body provided with haptics extending therefrom for centering said lens body when it is surgically implanted in the eye, said lens body having optical portions comprised of a unitary material and additionally comprising at least a center zone having a first diameter and inner and outer concentrically located ring correction zones having second and third diameters respectively, said center zone having a distance power correction, said inner zone having a near power correction and said outer zone having a distance power correction, said first and third diameters being pre-set so that under bright light conditions and low light conditions, substantially more than 50% of the light entering the eye passes through said center and outer ring correction zones, as the case may be.

2. The invention as defined in Claim 1 wherein said first diameter is in a range which extends from approximately one half to approximately equal to the average pupil diameter under expected bright light conditions.

3. The invention as defined in Claim 2 wherein the area of the inner concentric zone is greater than the area of the center zone.

4. The invention as defined in Claim 3 wherein said first diameter is approximately 2.1 millimeters.

5. The invention as defined in Claim 1 wherein the width of said inner concentrically located ring correction zone lies in the range from approximately 0.7 to 2.15 millimeters.

6. The invention as defined in Claim 5 wherein the diameter of the intra-ocular lens lies in the range of from 5 to 9 millimeters.

7. The invention as defined in Claim 6 wherein lens body is biconvex.

8. An intra-ocular lens comprising:

a lens body provided with haptics extending therefrom for centering said lens body when it is surgically implanted in the eye, said lens body having optical portions comprised of a unitary material and additionally comprising at least a center zone and inner and outer concentrically located ring correction zones, said center zone having a distance power correction and a diameter falling in a range of from less

than to approximately equal to, the average pupil diameter under expected bright light conditions, said inner ring correction zone having a near power correction and said outer ring correction zone having a distance power correction.

9. The invention as defined in Claim 8 wherein the diameter of said center zone is approximately 2.1 millimeters.

10. The invention as defined in Claim 8 wherein the width of said inner, concentrically located ring correction zone lies in the range of from approximately 0.7 to 2.15 millimeters.

11. The invention as defined in Claim 10 wherein the diameter of the intra-ocular lens lies in the range of from 5 to 9 millimeters.

12. The invention of Claim 11 wherein said lens body is biconvex.

13. An intra-ocular lens having a circumference which bears against the inner surface of the posterior lens capsule when the intra-ocular lens is surgically implanted in the eye, said lens having optical portions comprised of a unitary material and additionally comprising at least a center zone having a first diameter and inner and outer concentrically

located ring correction zones having second and third diameters respectively, said center zone having a distance power correction, said inner concentrically located ring correction zone having a near power correction and said outer concentrically located ring correction zone having a distance power correction, said first and third diameters sized so that under bright light conditions and low light conditions, substantially more than 50% of the light entering the eye passes through said center and outer correction zones, as the case may be.

14. The invention as defined in Claim 13 wherein said first diameter is in a range which extends from approximately one half to approximately equal to the average pupil diameter under expected bright light conditions.

15. The invention as defined in Claim 14 wherein the area of the inner concentric zone is greater than the area of the center zone.

16. The invention as defined in Claim 15 wherein said first diameter is approximately 2.1 millimeters.

17. The invention as defined in Claim 13 wherein the width of said inner concentrically located ring correction zone lies in the range from approximately 0.7 to 2.15 millimeters.

18. The invention as defined in Claim 17 wherein the diameter of said center zone is in the approximate range of 1 to 2.1 millimeters.

19. The invention as defined in Claim 18 wherein the outer diameter of the outer concentrically located ring correction zones exceeds the average pupil diameter under expected low light conditions.

20. The invention as defined in Claim 13 wherein said intra-ocular lens comprises an optic whose edges are adapted to bear against the inner surface of said posterior lens capsule.

21. The invention as defined in Claim 13 wherein said intra-ocular lens comprises an optic and an encircling haptic connected to said optic, said haptic adapted to bear against the inner surface of said posterior lens capsule.

FIG. 1.

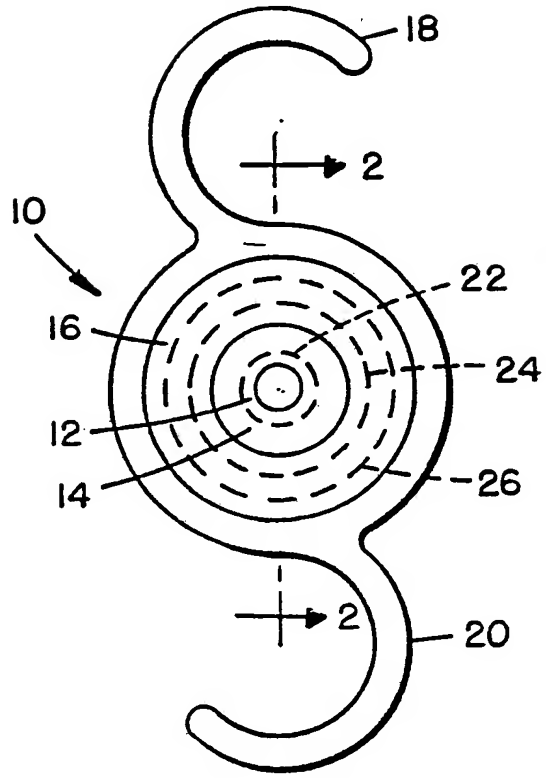


FIG. 3.

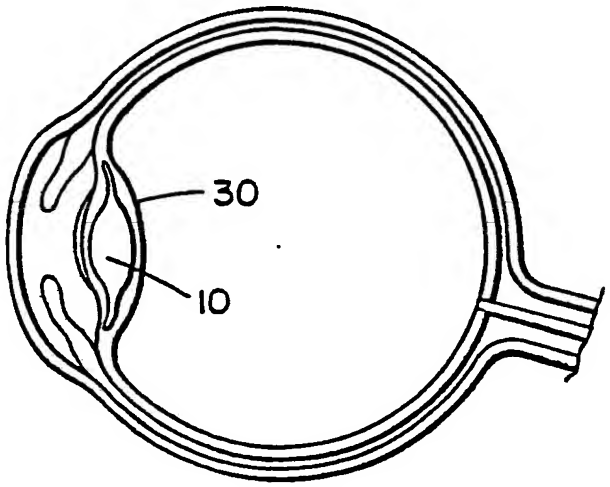


FIG. 2.

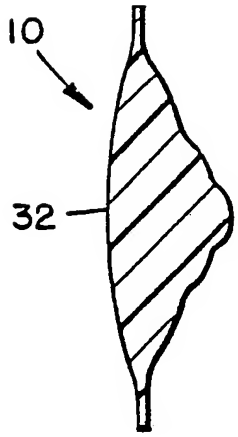


FIG. 4.

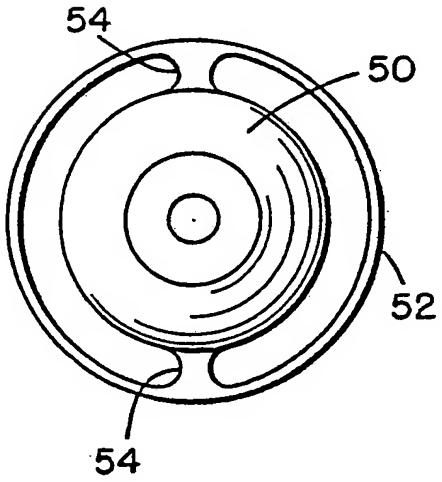


FIG. 5.

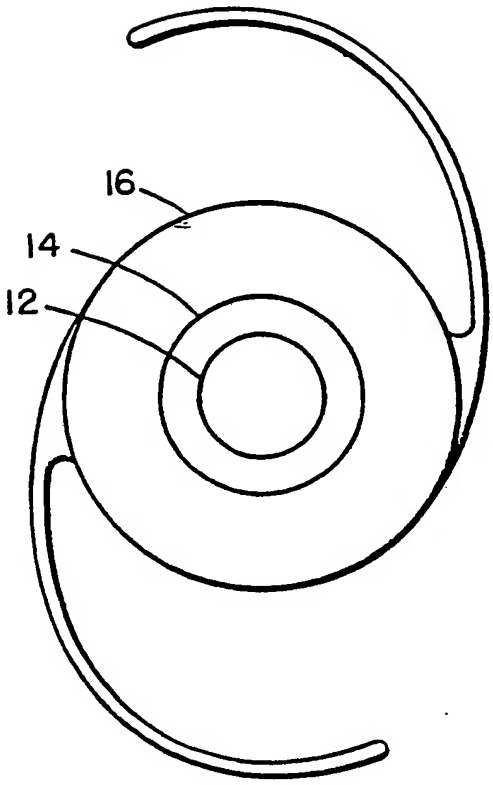


FIG. 6.

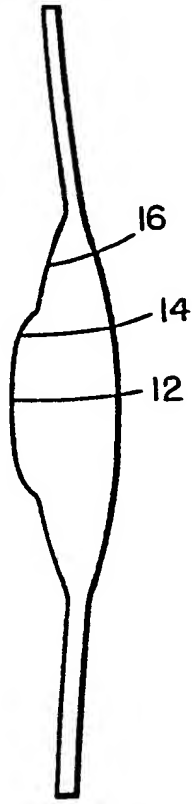
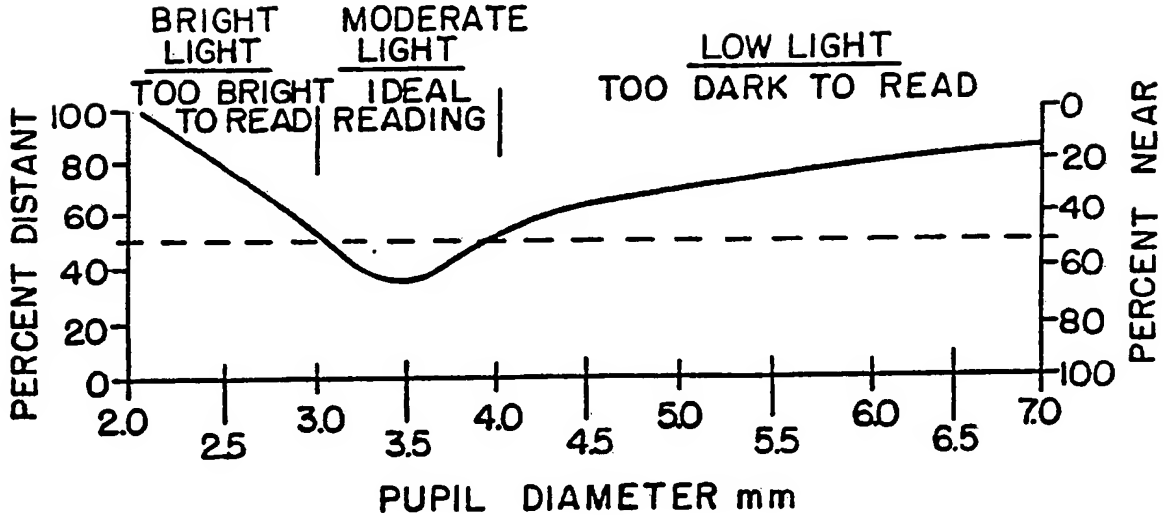


FIG. 7.



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US89/03054

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (4): A61F 2/16, G02C 7/04, G02C 7/06
U.S. Cl. 623/6, 351/161,168

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	623/6, 351/161,168,171

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	US, A, 4,556,998 (SIEPSER) 10 DECEMBER 1985 (See Abstract, column 5, lines 3-68, column 6, lines 1-68, column 7, lines 1-14 and Figures 2A and 4)	20
Y	US, A, 4636,211 (NIELSEN ET AL) 13 JANUARY 1987 (See column 1, lines 34-65,column 2, lines 16-38 and 55-68 and column 3, lines 1-10)	1-21
Y	DE, A, 3332313 A1 (TITMUS) 04 APRIL 1985 (See Figure 2, page 7, lines 21-22, page 8, in its entirety, page 9, lines 1-8, page 10, lines 9-14 and page 13, lines 6-24)	1-21
Y	WO, 86/03961 (VANNAS) 17 JULY 1986 (See Figures 7 and 10, page 1, lines 18-25, page 2, lines 7-23, page 3,lines 19-21, page 4, last paragraph, page 5, lines 1-2 and 10-15)	1-21

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
03 OCTOBER 1989	20 OCT 1989
International Searching Authority	Signature of Authorized Officer
ISA/US	Ronald Frinks

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

Y	N, Ocular Surgery News, issued 01 October 1987, "New Concepts in circular posterior chamber lenses" by Aziz Y. Anis, pages 16-18.(See entire article)	13-19,21

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers , because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers . , because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

3. ☐ Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.